amended, no claims have been added or cancelled so that claims 1-15 remain pending. No new matter has been introduced.

Claims 1 and 8 were rejected under 35 U.S.C. § 112, second paragraph. Applicants have amended the claims to more particularly point out and distinctly claim the subject matter. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-15 were rejected as anticipated by U.S. Patent Number 5,516,781 to Morris et al. (Morris). This rejection is respectfully traversed.

Morris discloses a method for preventing or treating hyperproliferative vascular disease in a mammal by administering an effective amount of an anti-proliferative (rapamycin) alone or in combination with mycophenolic acid. The delivery method may include the use of a stent. Specifically, Morris discloses the use of rapamycin in preventing smooth muscle cell hyperplasia, restenosis and vascular occlusion resulting from mechanically mediated injury. Essentially, Morris discloses treating or preventing hyperproliferative vascular disease in a mammal by administering an anti-proliferative effective amount of rapamycin to the mammal in any number of ways, including a stent. Morris also discloses the combination of rapamycin and mycophenolic acid to treat the same condition.

As is well established in patent law, anticipation exists only if all of the elements of the claimed invention are present

in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention, as claimed in amended independent claim 1, is directed to a method for preventing constrictive remodeling comprising a controlled delivery, by release from an intraluminal medical device, of a compound having anti-proliferative and anti-inflammatory properties in therapeutic dosage amounts, the compound substantially reducing in-lesion lumen loss both proximate and distal to the intraluminal medical device. The present invention, as claimed in amended claim 8, is directed to a drug delivery device for treating constrictive vascular remodeling. The device comprises an intraluminal medical device and a therapeutic dosage of an agent having anti-proliferative and anti-inflammatory properties releasably affixed to the intraluminal medical device for the treatment of constrictive vascular remodeling. The agent substantially reducing in-lesion lumen loss both proximal and distal to the intraluminal medical device.

Firstly, according to MPEP 2111.02 the "preamble is not given the effect of a limitation unless it breathes life and meaning into the claim." It is respectfully submitted that the preamble of claims 1 and 8 do in fact breath life and meaning into the claims. Claim 1 claims a method for preventing constrictive vascular remodeling and Claim 8 claims a drug delivery device for treating constrictive vascular remodeling.

Vascular remodeling is a different phenomenon than in-stent restenosis.

Secondly, Claim 1 goes on to claim a compound having anti-proliferative and anti-inflammatory properties in therapeutic dosage amounts that substantially reduces in-lesion lumen loss, both proximate and distal to the intraluminal medical device, and Claim 8 claims an agent having the same effect and the same purpose.

A rejection under 35 U.S.C. 102(b) may be overcome by persuasively arguing that the claims are patentably distinguishable from the prior art or by having an earlier priority date. Applicants choose to persuasively argue that the claims are clearly distinguishable.

Based upon a careful and complete review of Morris, one must concede that Morris fails to disclose or even remotely suggest preventing constrictive vascular remodeling or substantially reducing in-lesion lumen loss as claimed in independent Claims 1 and 8. As stated in the specification, negative or constrictive vascular remodeling may be quantified angiographically as the percent diameter stenosis at the lesion site where there is no stent to obstruct the process. In-lesion, as opposed to in-stent parameters are usually measured approximately 5mm on either end of the stent.

Since Morris fails to explicitly disclose this element of the claim, it must then be found to be inherent. MPEP 706.02 states that any feature not directly taught must be inherently

present. Applicants respectfully submit that no *prima facie* showing of inherency has been established. To paraphrase from Continental Can Co. v Monsanto Co. …(Fed. Cir. 1991), to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.

Morris does not inherently set forth in-lesion versus in-stent restenosis, nor does Morris set forth a potential treatment. At the time the Morris application was filed, the in-stent versus in-lesion phenomenon was not yet discovered, nor was it understood how uncoated stents, in general, prevented restenosis. Since Morris fails to inherently set forth these claimed elements, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-15 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application Number 09/850,233, claims 1-15 of, copending Application Number 09/850,507, claims 1-17 of copending Application Number 09/850,232, claims 1-14 of copending Application Number 09/850,365 and claims 1-15 of copending Application Number 09/575,480.

Applicants understand that these rejections are to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However,

in light of the amendments to the claims of the present invention and any potential amendments made to the claims of the cited applications, Applicants shall defer any arguments and/or actions until the applications actually issue.

Applicants would be willing to interview the present case if the Examiner so desires. Accordingly, the Examiner is invited to call the undersigned at (732) 524-2518 if such a call would facilitate the prosecution of this application.

The Amendment/Reply raises no new issues and places the application in form for allowance. Therefore, entry is proper and earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend the claims as follows:

1. (Twice Amended) A method for preventing constrictive vascular remodeling comprising a controlled delivery, by release from an intraluminal medical device, of [an anti-proliferative/anti-inflammatory] a compound having anti-proliferative and anti-inflammatory properties in therapeutic dosage amounts, the compound substantially reducing in-lesion lumen loss both proximate and distal to the intraluminal medical device.

8. (Twice Amended) A drug delivery device for treating constrictive vascular remodeling comprising:

an intraluminal medical device; and

a therapeutic dosage of an [anti-proliferative/anti-inflammatory] agent having anti-proliferative and anti-inflammatory properties releasably affixed to the intraluminal medical device for treatment of constrictive vascular remodeling, the agent substantially reducing in-lesion lumen loss both proximal and distal to the intraluminal medical device.